

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

PFIZER INC., WYETH LLC, PFIZER
PHARMACEUTICALS, LLC, PF PRISM
C.V., and PFIZER MANUFACTURING
HOLDINGS LLC,

Plaintiffs,

v. // CIVIL ACTION NO. 1:15CV4
(Judge Keeley)

MYLAN INC., AGILA SPECIALTIES
PRIVATE LTD., MYLAN PHARMACEUTICALS
INC.

Defendants.

ORDER GRANTING PLAINTIFFS' MOTION TO STAY THE
SECOND-FILED SUIT (DKT. NO. 21) AND STAYING THE CASE

On January 9, 2015, the plaintiffs, Pfizer Inc., Wyeth LLC, Pfizer Pharmaceuticals, LLC, PF Prism C.V., and Pfizer Manufacturing Holdings LLC (collectively, "Pfizer"), filed a complaint for patent infringement against defendants Mylan Inc., Agila Specialties Private Ltd., and Mylan Pharmaceuticals Inc (collectively, "Mylan") (Dkt. No. 1).¹ Mylan filed its answer and counterclaims on February 16, 2015 (Dkt. No. 16), and Pfizer filed its answer to the counterclaims on March 6, 2015 (Dkt. No. 20).

¹ On January 8, 2015, Pfizer had filed an identical complaint in the United States District Court for the District of Delaware, making the suit in this district a second-filed action (Dkt. No. 22 at 6).



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On March 6, 2015, Pfizer filed a motion to stay this case as a second-filed suit,² pending resolution of a jurisdictional dispute in the first-filed suit pending in the United States District Court for the District of Delaware, where discovery is already progressing (Dkt. No. 21). Mylan filed its response in opposition to Pfizer's motion on March 30, 2015 (Dkt. No. 36), and Pfizer filed its reply on April 16, 2015 (Dkt. No. 40). The motion is now fully briefed and ripe for disposition.

I. Background

Pfizer holds two patents³ and a new drug application ("NDA") for TYGACIL, a tetracycline class antibacterial for intravenous infusion indicated for the treatment of complicated skin and skin structure infections, complicated intra-abdominal infections, and community-acquired bacterial pneumonia in adults (Dkt. No. 1 at 7).

² A second-filed case, or protective suit, is usually filed by the patent holder to protect its entitlement to a thirty-month stay should the first-filed suit be dismissed.

³ Patent No. 7,879,828 ("the '828 Patent"), issued on February 1, 2011, and Patent No. 8,372,995 ("the '995 Patent"), issued on February 12, 2013, cover TYGACIL (Dkt. No. 1 at 7-8). Two additional patents cover TYGACIL, but are not the subject of the current litigation. See Orange Book, available at http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021821&Product_No=001&table1=OB_Rx (last updated March 2015).

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U.S. Food and Drug Administration, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, available at http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021821&Product_No=001&table1=OB_Rx (last updated March 2015).

On November 26, 2014, Mylan notified Pfizer that it had filed an abbreviated new drug application ("ANDA") containing a Paragraph IV certification that Pfizer's patents for TYGACIL are invalid, unenforceable, or will not be infringed by its ANDA. On January 9, 2015, Pfizer filed its complaint alleging patent infringement, and seeking various forms of relief, including: 1) a judgment that Mylan infringed the '828 and '995 patents; 2) a permanent injunction restraining Mylan from manufacturing, using, offering to sell, marketing, distributing, importing, or selling a generic version of TYGACIL; 3) an order stating that the effective date of any FDA approval of Mylan's ANDA should be after Pfizer's patents expire; 4) a judgment that Mylan's manufacture, use, offer for sale, marketing, distributing, importation, or sale of TYGACIL will infringe its patents; 5) damages; and, 6) reasonable attorneys' fees (Dkt. No. 1 at 15-16).

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On February 13, 2015, Mylan filed its answer and counterclaim, denying any infringement of Pfizer's patents, and countering that the patents are invalid (Dkt. No. 16 at 25). Mylan seeks a declaration that its manufacture, use, offer for sale, importation, or sale of its generic version of TYGACIL does not infringe Pfizer's patents, a declaration that the patents are invalid, and dismissal of Pfizer's complaint with prejudice, as well as attorneys' fees and costs. Id. at 28-29.

When Pfizer filed its motion to stay the second-filed case on March 6, 2015, it argued that this Court should stay the case under the first-to-file rule so that the first-filed suit in the District of Delaware could proceed (Dkt. No. 21 at 5). Following that, on March 30, 2015, Mylan filed a motion in Delaware seeking to dismiss the first-filed case based on lack of jurisdiction, a motion that remains pending (Dkt. No. 40-2 at 10). On April 9, 2015, Judge Sue Robinson issued a scheduling order, indicating her desire to progress with discovery despite the pending jurisdictional challenge (Dkt. No. 40 at 4-5).

As a result of all this, Pfizer contends that this Court should stay the second-filed suit until the jurisdictional dispute in Delaware is resolved, particularly given Judge Robinson's

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decision to proceed with that case and the pending interlocutory appeal before the United States Court of Appeals for the Federal Circuit.⁴ If the Federal Circuit rules that the District of Delaware has jurisdiction over Mylan, the case will proceed there. If Delaware lacks personal jurisdiction over Mylan, then the case can proceed in this Court, where there is no question that personal jurisdiction exists.

II. Applicable Law

The first-to-file rule is an equitable doctrine that "favors the forum of the first-filed action" Genentech, Inc. v. Eli Lilly and Co., 998 F.2d 931, 937 (Fed. Cir. 1993), abrogated on other grounds, Wilton v. Seven Falls Co., 515 U.S. 277, 115 S.Ct. 2137 (1995). The primary policies underlying the first-to-file rule are the avoidance of duplicative litigation, the promotion of uniformity of results, and the conservation of judicial resources. See Colorado River Water Conservation District v. United States,

⁴ The Federal Circuit recently granted Mylan's motion for interlocutory appeal of the District of Delaware's decisions to deny its motions to dismiss in AstraZeneca AB v. Mylan Pharms., Inc., No. 2015-117 (Fed. Cir. Mar. 17, 2015), and Acorda Therapeutics Inc. et al. v. Mylan Pharms. Inc. et al., No. 2015-124 (Fed. Cir. Mar. 17, 2015).

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424 U.S. 800, 817, 96 S.Ct. 1236 (1976); Cadle Co. v. Whataburger of Alice, Inc., 174 F.3d 599, 604 (5th Cir. 1999).

When two courts have concurrent jurisdiction in substantially identical cases, the court hearing the second-filed action generally defers to the court hearing the first-filed action. See Merial Ltd. v. Cipla Ltd., 681 F.3d 1283, 1299 (Fed. Cir. 2012). Courts usually consider three factors to determine whether the first-to-file rule applies. These include 1) chronology, 2) identity of parties, and 3) similarity of issues. Intersearch Worldwide, Ltd. v. Intersearch Group, Inc., 544 F.Supp.2d 949, 957 (N.D. Cal. 2008).

Importantly, in first-filed cases where jurisdiction is unsettled, courts have held that the first-to-file rule does not apply. See, e.g., Genentech, 998 F.2d at 938 (listing the absence of jurisdiction as a "sound reason that would make it unjust or inefficient to continue the first-filed action."); Orthmann v. Apple River Campground, Inc., 765 F.2d 119, 121 (8th Cir. 1985) (dismissing the first-filed action, where jurisdiction was "vigorously dispute[d]," to allow the second-filed action to progress).

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Some courts, however, have determined that jurisdiction in the first-filed case is just one factor to consider. See Cadle Co., 174 F.3d at 605 ("While the likelihood of a jurisdictional dispute in the first-filed court may be a factor to consider in applying the rule, resolving the dispute in favor of that court's jurisdiction is never a condition precedent to applying it."); Brower v. Flint Ink Corp., 865 F.Supp. 564, 570 (N.D. Iowa 1994) (noting that jurisdictional considerations are one of many factors when determining what circumstances are compelling enough to overcome the first-to-file rule).

The first-to-file rule is subject to various exceptions, including consideration of whether the balance of convenience weighs in favor of the second-filed court's continued exercise of jurisdiction over the suit, whether the suit is filed in bad faith, or whether the suit is filed for the purposes of forum shopping. EEOC v. Univ. of Pa., 850 F.2d 969, 976 (3d Cir. 1988); Ellicott Mach. Corp. v. Modern Welding Co., 502 F.2d 178, 181 (4th Cir. 1974). It is the province of the first-filed court, however, to determine "whether an exception to the first-filed rule applies." Touchstone Research Lab, Ltd. v. Anchor Equip. Sales, Inc., 294

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F.Supp.2d 823, 828 (N.D.W. Va. 2003) (quoting Citigroup Inc v. City Holding Co., 97 F.Supp.2d 549, 557 n.4 (S.D.N.Y. 2000)).

III. Legal Analysis

The prerequisites for applying the first-to-file rule, chronology, identity of parties, and similarity of issues, seem to be satisfied here. Intersearch Worldwide, Ltd., 544 F.Supp.2d at 957. The first-filed complaint was filed in the District of Delaware on January 8, 2015 (Dkt. No. 22 at 6). The second-filed complaint was filed in this Court on January 9, 2015, one day later (Dkt. No. 1). Furthermore, the parties in the first-filed case are the same parties as those in this case (Dkt. No. 22 at 6). Finally, the complaints, the patents, and the allegedly infringing products are all identical. Id. Shire U.S., Inc. v. Johnson Matthew, Inc., 543 F.Supp.2d 404, 408-09 (E.D. Penn. 2008) (noting that the subject matter requirement is met where the actions involve the same patent and the same infringing product).

Mylan argues that the first-to-file rule should not apply due to the jurisdictional dispute in play in the District of Delaware, particularly given the status of defendant Agila, an Indian corporation with a principal place of business in India. Although this Court previously has denied motions to stay where jurisdiction

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in the first-filed action was vigorously disputed and the case was not progressing, here, the first-to-file rule squarely applies. See Novartis Pharma. Corp. v. Mylan Inc., Case No. 1:14CV106, Dkt. No. 47 (N.D.W. Va. Jan. 27, 2015) (Keeley, J.) (finding that the first-to-file rule did not apply due to a vigorous jurisdictional dispute); Novartis Pharma. Corp. v. Mylan Inc., Case No. 1:14CV111, Dkt. No. 38 (N.D.W. Va. Jan. 29, 2015) (Keeley, J.) (same).

Simply put, the factual scenario in this case differs significantly from that in the two Novartis cases. There, it was significant that Mylan could be "faced with the possibility of both a stay in this case and a long wait in the District of Delaware should that court choose to withhold its decision on Mylan's motion to dismiss until the Federal Circuit decides the interlocutory appeal in AstraZeneca." (Case No. 1:14CV111, Dkt. No. 38 at 14). Here, although Judge Robinson has not yet ruled on Mylan's motion to dismiss, she has expressed her desire to move the case forward into discovery (Dkt. No. 40). Unlike the situation in Novartis, where the parties would potentially face a lengthy delay in proceedings, the first-filed suit is likely to proceed under Judge Robinson.

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Importantly, however, the considerations underlying the first-to-file rule require that this Court grant Pfizer's motion to stay. The first-to-file rule "is a doctrine of federal comity, intended to avoid conflicting decisions and promote judicial efficiency." Merial, 681 F.3d at 1299. It would hardly promote efficiency or uniformity to proceed with a second case in this district when the first-filed case is already proceeding in the District of Delaware.

This case also differs slightly from Acorda Therapeutics, Inc. v. Mylan Pharmaceuticals, Inc., Case No. 1:14CV139 (Keeley, J.), where Mylan filed a motion to stay in the first-filed suit, which Chief Judge Stark of the District of Delaware denied. In Acorda, this Court found it significant that Chief Judge Stark had already considered Mylan's argument urging a stay, and denied the motion (Case No. 1:14CV139, Dkt. No. 59 at 8). Although that factor is not present here, the Court finds it significant that Judge Robinson is proceeding with discovery in the face of Mylan's jurisdictional challenge, going so far as to schedule the case for trial.

Should Judge Robinson or the United States Court of Appeals for the Federal Circuit later conclude that Mylan is not subject to personal jurisdiction in the District of Delaware, the case can

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easily be transferred to this district. Thus, granting the motion to stay does not leave Mylan without a remedy.

For the reasons discussed, the Court 1) **GRANTS** Pfizer's motion to stay the second-filed suit (Dkt. No. 21); 2) **STAYS** the case; 3) **CANCELS** the scheduling conference, currently set for **May 14, 2015**; and 4) **SCHEDULES** a telephonic status conference on **Thursday, October 22, 2015, at 1:00 P.M.** In the interim, the parties are **ORDERED** to inform the Court of any developments regarding the outcome of Mylan's interlocutory appeal or otherwise affecting its jurisdictional status in the District of Delaware.

It is so **ORDERED**.

The Court directs the Clerk to transmit copies of this Order to counsel of record.

DATED: April 24, 2015.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE